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K030706
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510(k) Summary

This 510(k) Summary for the EBI® DynaFix® Compression Bone Screws is provided as required per Section 513(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Frederic Testa
Phone: (973)299-9300, ext. 2208

Date prepared: March 3, 2003

2. **Proprietary Name:** EBI® DynaFix® Compression Bone Screw

Common Name: Internal Fixation Device

Classification Names: Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR 888.3040

3. **Predicate or legally marketed devices that are substantially equivalent:**

- Zimmer Herbert Screw (K792022)
- Acumed Acutrak (K930834)
- Millennium HBS Headless Bone Screw (K020791)

4. **Description of the device:** The EBI® DynaFix® Compression Bone Screw is intended to be inserted across the fracture site. The EBI® DynaFix® Compression Bone Screw will provide compression across the fracture site.

5. **Intended Use:** The EBI® DynaFix® Compression Bone Screws are indicated for fusions, fractures, or osteotomies of the upper and lower extremities.

6. **Materials:** The components of the System may be manufactured from stainless steel as per ASTM F-899.

7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the EBI® DynaFix® Compression Bone Screws and other currently marketed internal fixation systems. It is substantially equivalent* to the predicate device in regards to intended use, materials, and function.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Mr. Frederic Testa, RAC
Senior Regulatory Affairs Specialist
EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

Re: K030706
Trade/Device Name: EBI® DynaFix® Compression Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 3, 2003
Received: March 6, 2003

Dear Mr. Testa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

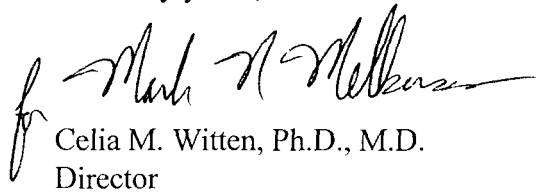
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K030706

Device Name: EBI® DynaFix® Compression Bone Screw

Indications For Use:

The EBI® DynaFix® Compression Bone Screws are indicated for fusions, fractures, or osteotomies of the Upper and Lower Extremities.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milham

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030706